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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,098	12/28/2001	Geoffrey P. Symonds	J&J 2084	1700

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EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/035,098

Applicant(s)

SYMONDS ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 21, 22, 24-30, 32-40, 58, 60, 63-66 and 68-88 is/are pending in the application.  
4a) Of the above claim(s) 4-6, 34-40, 58, 60, 63, 68 and 79-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3, 21, 22, 24-30, 32, 33, 64-66, 69-78 and 88 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Applicant's election with traverse of Group I in the reply filed on 31 May 2006 is acknowledged. The traversal is on the ground(s) that the claims have been divided in a manner which is not reasonable, because there are, among other alleged problems, two lines of claims directed to related types of RNAs. In support, applicants point to the fact that claim 4 is dependent from claim 1, yet they are in different groups. It is noted that these arguments are based on claim amendments which were not pending in front of the examiner at the time the previous restriction requirement was mailed. For example, it was only in the most recent amendment of 31 May 2006 that claim 4 was amended to be dependent from claim 1. Claim 1 is considered to be a linking claim that links, among other elements, dsRNA's that comprise separate ribonucleic acids, and dsRNA's that comprise a single hairpin dsRNA. These groups are properly restricted, since one does not embrace the other, they are not disclosed as useful together, and they have distinct structures. Furthermore, a search for one would not necessarily return art against the other which therefore constitutes a serious burden on office to search both in a single application.

Group I is considered to be characterized by dsRNA's that comprise separate ribonucleic acids, and is considered to be the elected invention given applicants' election of Group I. The subject matter of groups II-VIII (claims 4-6, 34-40, 58, 60, 63, 68, 79-87) as well as subject matter which remains in pending claims 1-3, 21, 22, 24-30, 32, 33, 64-66, 69-78 and 88 drawn to the hairpin dsRNA complex as defined in claim 4 are withdrawn as being directed to nonelected inventions. Since the appearance of new claims necessitating further restriction has accompanied each response to a restriction requirement to date, applicants arguments regarding restriction will

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be further responded to upon election of a single Group wherein no further claims are newly presented that require restriction. Claims 1-3, 21, 22, 24-30, 32, 33, 64-66, 69-78 and 88 are further restricted as defined below.

Turning briefly to a misperception apparent in applicant's arguments, it appears that applicants have interpreted the delineation of separate Groups as being drawn only to their narrowest recited combination, thereby excluding broader, embracing embodiments. For example, applicants have indicated their belief that claim 58 cannot be put logically into any particular Group, and that said claim "is only mentioned in Group VII, a group which requires the presence of polyadenylation signal and a hammerhead ribozyme" (emphasis added, applicants arguments page 11). It should be clarified that, while the various Groups are defined by the narrowest embodiment of that invention, linking claim practice requires that any claim which broadly embraces the elected narrow embodiment would also be examined. Therefore, some exist within Group VII that do not require the presence of a polyadenylation signal and a hammerhead ribozyme. In other words, when each Group is defined, only the narrowest embodiment is presented as a descriptor, but the broader, embracing claims are examined as well.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the multiple additional ribonucleic acids sequences that enhance the ability of dsRNA to alter the expression of the gene encoding and mRNA molecule listed in claims 72, 74-78, and 88 are subject to restriction. The instant

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"enhancing" sequences are considered to be unrelated, since each enhancing sequence claimed is structurally and functionally independent and distinct, and since any one does not embrace any other, or is not an obvious variant of another.

Furthermore, a search of more than one (1) of the enhancing sequences claimed in the above listed claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed enhancing sequences. In view of the foregoing, one (1) enhancing sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) specific enhancing sequence from the group consisting of VAI, HIV-1, TAR, EBER-1, Alu, Tat, E3L, reovirus p3 protein, vaccinia virus pk3, PKR, negative proteins, p58, v-erbB, sos, or activated ras.

### *Species*

This application contains claims directed to the following patentably distinct species: cells comprising either a nucleic acid from HIV or cells that are neoplastic, as recited in either of claim 28 or claim 29.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 24 or 25 are generic.

This application contains claims directed to the following patentably distinct species: cells comprising a plasmid, adenoviral, an adenoassociated viral, or retroviral vector as recited in claim 32.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 30 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

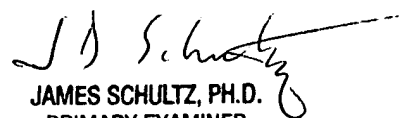
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JDS

  
JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER